IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/695,295
Applicant:	Gonzales et al.
Filed:	October 28, 2003
TC/A.U.:	3763
Confirmation No.:	4188
Examiner:	Quynh-Nhu Hoang Vu
Docket No.:	A-2966-AU
Customer No.:	21378

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. 41.41

Sir:

In accordance with an Examiner's Answer dated January 20, 2010, Applicants submit this Reply Brief, which is timely filed by March 22, 2010 because March 20, 2010 falls on a weekend.

I. INDEPENDENT CLAIMS 1 AND 10

A. The Valve of Abramson Does Not Perform the Recited Functions

The Examiner states that the functional limitations in claims 1 and 10 "do not impose any structural limitation upon the claimed apparatus which differentiates it from prior art references disclosing the structural limitations of the claim". Examiner's Answer at 4, 5–6. Because the valve **10** of Abramson is not capable of performing and/or does not perform the functions recited in claims 1 and 10, as discussed below, claims 1 and 10 are *structurally* distinguishable from the valve **10** of Abramson.

1. An Instrument Cannot Be Inserted Through the Valve Described by the Examiner

The Examiner states "Abramson clearly discloses a ridge **31** and a groove **32** to create a locking force tending to inhibit movement of the instrument". Examiner's Answer at 6. The Examiner also states that "Abramson discloses . . . the proximal housing portion is not adjustable axially relative to the distal housing portion." Examiner's Answer at 3. As illustrated in FIG. **1** of Abramson, the annular ridge **31** on the outside of member **11** engages the annular groove **32** on the inside of member **12**. Abramson at 3:1–5. Consequently, the locking force generated by the ridge **31** and the groove **32** *cannot be reduced in the device of Abramson*.

A consequence of the Examiner's theory, when advancing an instrument into the valve **10**, the tip **41** of an instrument experiences a *locking force that inhibits its movement* when the tip **41** reaches the valve disk **20**.[1] As a result, the tip **41** *cannot be advanced further into the valve 10*, and consequently, cannot be inserted *through* the valve **10**. Instead, the tip **41** is trapped by the valve disk **20**, thereby preventing a user from inserting an instrument *through* the valve **10** as recited in the claims.

2. The Slit Cannot Form a Seal Around an Instrument

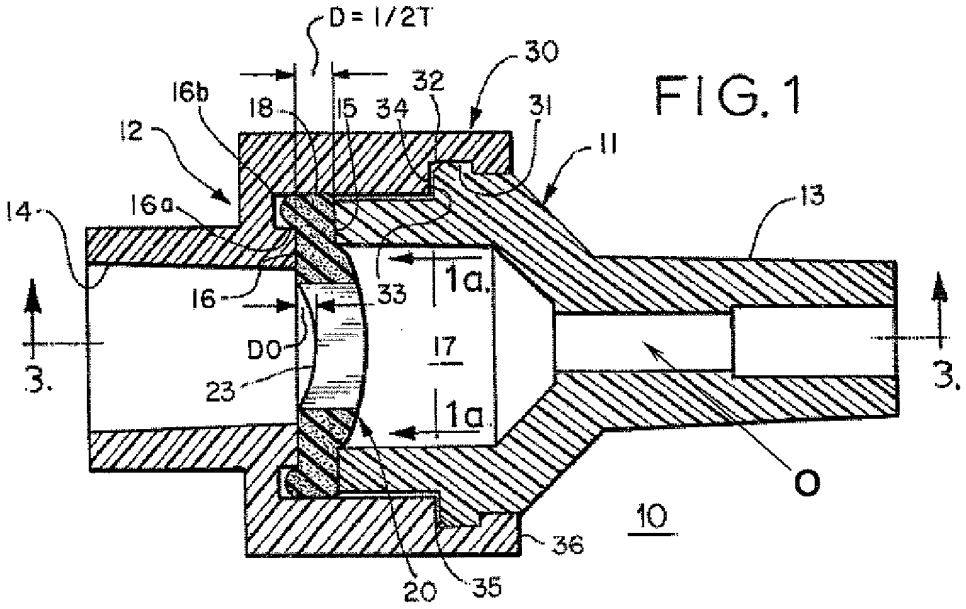
The Examiner argues "Abramson clearly shows in Fig. 3 that the instrument (syringe S) is not only inserted into the top part of the valve 20 but also able to insert into the valve, col. 5, lines 29–30." Examiner's Answer at 5. Neither the cited portion of Abramson nor any other

[1] Applicants note that the Examiner interprets "inhibits movement" as "preventing movement". Examiner's Answer at 4 ("in order to create a locking force *for preventing movement of the instrument*") (emphasis added).

portion discloses or suggests that any component in Abramson seals *around* an instrument as recited in the claims.

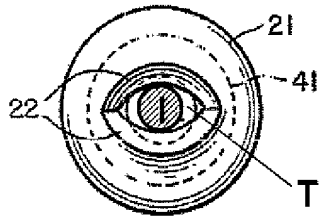
Claim 1 recites in part "the seal material including a gel having non-compressible characteristics, the gel having characteristics for creating a pressure on an instrument extending through the valve to form a seal *around* the instrument". Claim 10 is similar. The Examiner characterizes the valve disk **20** as corresponding to the recited "seal material". The Examiner states "when the slit valve 22 is opened, the valve 20 still seals around the male connector 40 of syringe." Examiner's Answer at 5. The slit **22** of the valve disk **20** cannot seal around an instrument inserted *through the valve **10***, as discussed below.

A version of FIG. **1** of Abramson illustrating a valve outlet **O** of the valve **10** is set forth below:



A diameter of an instrument **I** that can be inserted *through* the valve **10** can be no larger than the diameter of the outlet **O** because the instrument must extend through the outlet **O**. As shown in FIGS. **1**, **1a**, and **2**, the slit **22** is wider than the diameter of the outlet **O**. Modified FIG. **3a** below illustrates an end view of the valve disk **20** with the instrument extending through the slit **22**:

FIG. 3a



In extending through the slit **22**, the instrument **I** props open the slit **22** to create an eye-shaped opening, with the instrument at the center corresponding to the iris, and two generally triangular regions **T** on the left and right of the instrument corresponding to the white or sclera of the eye-shaped opening. The portions of the slit **22** defining the triangular regions **T** do not seal *around* the instrument **I**. Instead, the triangular regions **T** are openings through the valve disk **20**. Consequently, the slit **22** of the valve disk **22** cannot seal *around* any instrument **I** that can be inserted through the valve **10** as recited in the claims.

3. Applying Pressure to the Disk of Abramson Opens the Slit in the Valve Disk Instead of Creating a Locking Force

The Examiner argues that neither claim 1 nor claim 10 recites "increasing pressure on a seal material to form a seal around an instrument". Examiner's Answer at 4. The Examiner states that claim 1 recites only "creating (but not increasing) pressure on an instrument". *Id.* Claim 1 recites in part "the proximal housing portion is adjustably movable axially relative to the distal housing portion *to increase the pressure of the incompressible gel on the instrument* and to create a locking force tending to inhibit movement of the instrument relative to the valve." Claim 10 recites a similar feature. As discussed in the Appeal Brief and illustrated in FIGS. **3** and **3a** of Abramson, applying pressure to the valve disk **20** of Abramson *opens* the slit **22**, thereby permitting fluid flow therethrough. Appeal Brief at 7. Opening the slit **22** *releases* pressure on any instrument extending through the slit **22**, which is contrary to the function recited in claims 1 and 10. As discussed in greater detail below, neither Abramson nor any of the other cited references discloses or suggests increasing the pressure of any material on an instrument.

B. The Examiner Confuses Inserted Into with Inserted Through

Applicants argue that Abramson does not disclose or suggest inserting an instrument through the valve **10**. Appeal Brief at 7. The Examiner responds "Abramson clearly slows in Fig.

3 that the instrument (syringe S) is not only inserted into the top part of the valve 20 but also insert into the valve 20, col. 5, lines 29–30." Examiner's Answer at 7. The Examiner identifies the valve **10** as corresponding to the recited "valve". Examiner's Answer at 3 ("the proximal housing portion is adjustably movable axially relative to the distal housing portion to increase the pressure of the *seal/valve 10* on the instrument") (emphasis added). Abramson does not disclose or suggest an instrument extending *through* the valve **10**. The Examiner implicitly acknowledges this fact in using "into" in the Examiner's Answer rather than "through" in the above cited passage, as well as in other parts of the Examiner's Answer. *See, for example,* Examiner's Answer at 5, 6.

Abramson also discloses that the syringe **S** does not extend through the valve **10** as illustrated in FIG. **3** and described in the Specification:

> In accordance with *one of the important features of the present invention* the female connection **14**, on the member **12**, is axially aligned with the disc **20** and adjacent the "underside" **23** of the dome portion of the disc and so spaced with respect thereto that *when a cooperating male connector is inserted into the female connection **14**, and pressed into tight seated condition, the tip of the male connection engages the domed portion of the disc* to bow the same outwardly accompanied by spreading of the slit to permit axial flow of fluid through the through-opening **17**
>
> Abramson at 3:55–65 (emphasis added)

Consequently, the male connection **40** tightly seats with the female connection **14**, thereby preventing any further advancement thereof *before the tip **41** extends through the valve **10***.

The Examiner also appears to refer to the valve disk **20** as corresponding to the recited "valve". Examiner's Answer at 5, 6, 7. Abramson also does not support this erroneous claim interpretation because Abramson also does not disclose or suggest an instrument extending *through* the valve disk **20**, or even *into* the slit **22** of the valve disk **20**. *See, for example,* Abramson at claim 1 ("the tip of the male connector sealingly engages the dome of the disc to bow the same outwardly accompanied by spreading of the slit *but short of penetration thereof*"); claim 2 ("the tip of the male connection sealingly engages the domed portion of the disc to bow the same outwardly accompanied by spreading of the slit *but short of axial penetration thereby*"); claim 5 ("the tip of the male connector engages the domed portion of the disc to bow the same outwardly *but short of penetration thereof*"). As discussed above, FIG. **3** of Abramson illustrates

the maximum extent that the syringe tip **41** enters the valve **10**. The valve disk **20** actually bows away from the tip **41**, displacing the slit **22** away from the tip **41**. Also, as illustrated in FIG. **3a** of Abramson, the tip **41** is larger than the opening of the slit **22**. Consequently, the tip **41** is incapable of extending either into or through the slit **22**.

C. The Examiner Is Engaging in Hindsight Reconstruction

In response to the Applicant's argument that the Examiner is engaging in impermissible hindsight reconstruction in combining the cited references, the Examiner simply reproduces a portion of M.P.E.P. 2145(X)(A) and cites no actual evidence to the contrary. Examiner's Answer at 10. M.P.E.P. 2145(X)(A) provides that "so long as [the judgment of obviousness] takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and *does not include knowledge gleaned only from applicant's disclosure*, such a reconstruction is proper."

1. None of the Cited References Discloses or Suggests Creating Pressure on an Instrument

The Examiner's reason for combining Abramson with Weinstein or Brustad is "in order *to increase the pressure on an instrument* and *enhance the sealing* characteristic." Examiner's Answer at 3 (emphasis added). Claim 1 recites in part "the gel having characteristics *for creating a pressure on an instrument* extending through the valve *to form a seal* around the instrument". The Examiner does not cite either Weinstein or Brustad as disclosing creating pressure on an instrument. The only pressure disclosed in Weinstein is "arterial pressure". Weinstein at 1:26, 2:22–23, 3:13. The term "pressure" does not appear in Brustad. The Examiner provides no basis for combining the Abramson with Weinstein or Brustad that is not based solely on knowledge gleaned from the pending application and claims.

2. None of the Cited References Discloses or Suggests Creating a Locking Force on an Instrument

The Examiner argues that Abramson discloses a locking force tending to inhibit movement of an instrument. Examiner's Answer at 6 ("Abramson clearly suggest that locking means 31 and 32 (Figs. 1–5) is creating a locking force tending to inhibit movement of an instrument."); 8. As discussed in the Appeal Brief, the Examiner does not cite any actual disclosure in either Abramson or Johnson of the recited "locking force". Appeal Brief at 9–10.

The Examiner's reason for combining Abramson with Johnson is "in order *to create a locking force for preventing movement of the instrument relative to the valve*." Examiner's Answer at 4 (emphasis added). Claim 1 recites in part "the proximal housing portion is adjustably movable axially relative to the distal housing portion ... *to create a locking force tending to inhibit movement of the instrument relative to the valve*." The Examiner does not even attempt to explain why one skilled in the art would want to inhibit movement of an instrument relative to a valve. Again, the only reasonable conclusion is that Examiner's reason for combining Abramson with Johnson is wholly derived from knowledge gleaned the pending application and claims.

D. Abramson Discloses a Fluid Handling Valve

The Examiner argues that "Abramson clearly discloses that the domed construction is that the valve is capable of sealing extremely high pressure on the domed side." Examiner's Answer at 4. The Examiner cites Abramson's disclosure that the valve **10** can maintain high pressure in mechanical devices, for example, the cuff of an endotracheal tube. *Id.* Because neither claim 1 nor claim 10 recites this feature, the cited ability of the valve **10** to seal high pressures is irrelevant to the appealed claims.

Maintaining pressure in the cuff of an endotracheal tube requires sealing air within the cuff, which is a task for a fluid handling valve. Indeed, Abramson repeated discloses that the valve **10** is a fluid handling valve. *See, for example,* Abramson at Abstract ("*In injecting fluids* into the body or *in withdrawal of fluids* therefrom using a catheter"); Abstract ("It is an object of the present invention to provide a valve for use with a catheter or the like which is highly reliable in *operation with all types of fluids*, both liquid and gaseous"); 3:63–65 ("accompanied by spreading of the slit *to permit axial flow of fluid* through the through-opening **17**."); 4:6–8 ("accompanied by spreading of the slit so that a free passage is established between the conduits **17, 42** *for passage of fluid* in either direction."); 4:18–19 ("it is unnecessary for the fluid to make two or more abrupt 90° bends in traversing the valve."); 4:21–22 ("the present valve minimizes turbulence and throttling *of the fluid*"); 4:22–23 ("Where the *fluid* being handled is blood,"); 5:1–3 ("*no fluid is lost through the valve* incident to opening it or closing it."). No where does Abramson disclose or suggest the instrument access valve recited in the claims. Appeal Brief at

7. Consequently, one skilled in the art would understand Abramson as disclosing a fluid handling valve, not an instrument access valve.

E. Abramson Does Not Disclose or Suggest Adjustability Between a First Housing Portion and a Second Housing Portion

The Examiner asserts that Applicants are attacking the references individually where the rejections are based on a combination. Examiner's Answer at 7. With respect to Applicants' argument that Abramson does not disclose or suggest adjustability between a first housing portion and a second housing portion, Applicants' argument directly addressed the Examiner's finding that "Abramson discloses a surgical valve comprising . . . a ridge and groove 31, 32 (Figs. 1–5) are the means adjustably moving the proximal housing portion axially relative to the distal housing portion". Examiner's Answer at 3. The Examiner is not citing a combination of references.

The Examiner does make a contradictory statement that "the proximal housing portion [of Abramson] is not adjustable axially relative to the distal housing portion." Examiner's Answer at 3. Applicants are obligated to address each of the Examiner's contentions, however.

F. Abramson Does Not Disclose or Suggest a Non-Compressible Rubber

In response to the Applicants' position that Abramson does not disclose or suggest a non-compressible rubber, the Examiner states that "claim 1 only requires the material having non-compressible characteristics." Examiner's Answer at 7. The Examiner refers to Abramson as defining "rubber" as "not limited to natural or synthetic rubber but includes rubber-like plastics having similar durometer characteristics." *Id.* The Examiner then argues that "synthetic rubber such as silicone is also having non-compressible characteristics also. Examiner's Answer at 7–8. Abramson does not disclose silicone. Moreover, Abramson's definition is completely irrelevant to the point that Abramson does not disclose or suggest a non-compressible natural rubber, a non-compressible synthetic rubber, or a non-compressible rubber-like plastic. Abramson only requires that the material is "soft". One method for making a material soft is to make it compressible, for example, as a foam.

The only basis under which Abramson could be found to disclose a non-compressible rubber is under the doctrine of inherency. M.P.E.P. 2112(IV). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in

the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) (citations omitted). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner has not met the burden of establishing that the soft rubber of Abramson is inherently non-compressible.

G. Abramson Does Not Disclose or Suggest a Distal Guide Facilitating Retrograde Insertion of an Instrument

In response to Applicants' argument that Abramson does not disclose or suggest a "distal guide tube facilitating retrograde insertion of the surgical instrument into the surgical seal" as recited in claim 1, the Examiner states "the device structure of Abramson is similar to the device structure of claimed invention. Therefore, it is capable of performing this function above. As noted that, there is no different between the device of claimed invention and Abramson below:", followed by the following illustration:

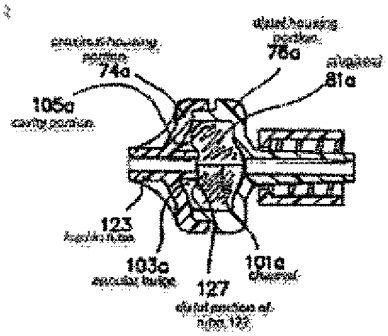


FIG. 7

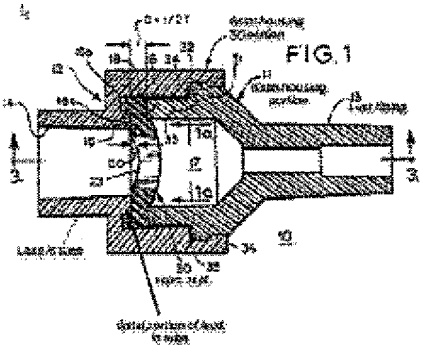


FIG. 1

As discussed above, Abramson does not disclose or suggest insertion of an instrument through the valve **10** in any direction. Also as discussed above, the valve **10** of Abramson according to the Examiner's proposal would be inoperative as an instrument access valve. Consequently, Abramson does not disclose or suggest even retrograde insertion of an instrument.

Furthermore, juxtaposing drawings is not a substitute for analysis, which reveals that the valve **10** of Abramson does not comprise the recited "distal guide". Using the terminology of the

above drawings, the Examiner apparently characterizes the Luer fitting **13** of Abramson as corresponding to the unlabeled distal guide on the right side of FIG. 7 of the present application. As shown in FIG. **7**, the narrow distal guide terminates at the distal end of the channel **101***a*. Consequently, the distal guide steers an instrument inserted from the right side thereof directly into the channel **101***a*. FIG. **1** of Abramson illustrates a Luer fitting **13** that terminates at a right side of a central through-opening **17**, and the valve disk **20** on the left side. The width and diameter of the central through-opening **17** are large and about equal to each other. An instrument inserted through the Luer fitting **13** must traverse width of the central through-opening **17** where it would likely go off-axis and completely miss the slit **22** of the valve disk **20** because it is not radially constrained by the width thereof. Consequently, the Luer fitting **13** does not facilitate retrograde insertion of an instrument.

H. The Examiner Interprets the "Creating Pressure" As "Increasing Pressure"

The Examiner asserts that "claim 1 only requires that the gel having characteristics for creating (but not increasing) pressure on an instrument." Examiner's Answer at 4. The Examiner himself interprets "creating pressure" as "increasing pressure". The Examiner states that it would have been obvious to combine Abramson with Weinstein or Brustad "in order *to increase the pressure* on an instrument and enhance the sealing characteristic." Examiner's Answer at 3 (emphasis added) Consequently, the Examiner is interpreting "creating pressure" with "increasing pressure".

I. The Examiner Has Not Explained How Abramson Could Be Combined with Weinstein

In response to Applicants argument of no reasonable expectation of success in combining Abramson with Weinstein, the Examiner simply states "The benefit of using gel of Weinstein into the device of Abramson is that including the benefits of providing high viscosity gel and sealing characteristics." Examiner's Answer at 9. The Examiner still has not explained how one skilled in the art would physically replace the soft rubber disk valve **20** of Abramson with the liquid gel **30** of Weinstein. Equally unclear is how such a device would continue to function as the fluid valve described in Weinstein, for example, opening in response to impingement of a syringe tip thereon, or even permitting fluid flow therethrough. Notably, the reasonable expectation of success must be found in the cited references or must be known to one skilled in

the art. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The Examiner has not cited any reference disclosing or taken official notice of a reasonable expectation of success in the combination.

J. The Gel of Weinstein Must Create a Locking Force Under the Examiner's Rationale

In response to Applicants' argument that Weinstein does not disclose or suggest increasing pressure of the gel or creating a locking force tending to inhibit movement of an instrument, the Examiner asserts that Applicants are attacking the references individually where the rejections are based on a combination Examiner's Answer at 8. The combination of Weinstein with Abramson and Johnson proposed by the Examiner *requires* that increasing pressure of the gel of Weinstein creates a locking force tending to inhibit movement of an instrument, irrespective of how the pressure is increased. As discussed in the Appeal Brief, Weinstein discloses a liquid gel **30** disposed in a chamber. Appeal Brief at 9. One skilled in the art would not understand that increasing the pressure on the liquid gel **30** of Weinstein would create a locking force on an instrument extending through the gel-filled chamber. In fact, Weinstein suggests the opposite because "gel **30** provides a lubricating coating to catheter **32** and any other elongated member that passes through the catheter introducer **10**, *to facilitate the lubricity and easy advancement thereof*." Appeal Brief at 9–10.

K. Claims 2, 4, and 5

The Examiner maintains the rejection of claims 2, 4, and 5 despite failing to make a *prima facie* case of obviousness against any of these claims. Examiner's Answer at 10. The Examiner's failure to establish *prima facie* cases against any of claims 2 and 4–5 was pointed out in the Appeal Brief. Appeal Brief at 11. In particular, the Examiner has not identified any disclosure or suggestion in any reference of the subject matter recited in claims 2, 4, or 5. Consequently, the rejection of claims 2 and 4–5 is contrary to law.

II. CLAIM 6

A. The Valve Disk and Slit of Abramson Do Not Correspond to the Recited Seal Material and Channel

Claim 6 recites in part:

> a subassembly including the seal material disposed in the gel cavity, *the seal material being configured with the channel in an open state*; and

a second housing portion disposed in juxtaposition to the first housing portion and *applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state*.

Briefly, the cited portion of claim 6 provides that the seal material comprises a channel in an open state until a sufficient force is applied on the seal material by a second housing portion, whereupon the force closes the channel.

The Examiner characterizes the valve disk **20** of Abramson as corresponding to the recited "seal material" and the slit **22** as corresponding to the "channel". Examiner's Answer at 10. The Examiner does not cite any disclosure or suggestion in Abramson corresponding to the "open state" of claim 6. FIG. **2** of Abramson illustrates the valve disk **20** in a state in which neither the cylindrical male member **11** nor the cylindrical female member **12** is not applying a force thereon. The slit **22** is not in an open state. Consequently, the valve disk **20** and slit **22** do not correspond to the recited "seal material" and "channel" and claim 6 is allowable over the cited references for at least this reason.

B. Abramson Does Not Disclose or Suggest A Second Housing Portion Applying a Force to the Seal Material

The Examiner states that "the device of Abramson is capable of performing this function such as when the male connector 40 of syringe S is touching the surface of valve 20, but not pressing hard enough, when the valve 20 still is in the closed condition." Examiner's Answer at 11.

Claim 6 defines a state in which the channel is in the open state –absent a sufficient force applied by the second housing portion – and a state in which the channel is in the closed state – present a sufficient force applied by the second housing portion. As such, the cited features of claim 6 are *structural*, rather than *functional* because they describe the structure and physical relationships of the recited components. As discussed above, the Examiner has not identified any disclosure or suggestion corresponding to the channel in the open state. With respect to the closed state, claim 6 provides that *the second housing portion* applies the sufficient force. The Examiner does not address any interaction between the valve disk **20** and a second housing portion at all. Furthermore, the scenario imagined by the Examiner does not convert the slit **22**

from an open state to a closed state. For at least this reasons, claim 6 is allowable over the cited references

C. The Examiner's Reasons to Combine the References Continue to Be Irrelevant to Claim 6

The Examiner states that "Applicant does not specifically point out the improper or irrelevant reasons." Examiner's Answer at 11. As discussed above and in the Appeal Brief, each of the Examiner's reasons for combining the cited references is impermissible.

D. Dependent Claims 7–9

The Examiner maintains the rejection of dependent claims 7–9. Examiner's Answer at 12. Applicants submit that the rejections continue to be improper because the Examiner has not established a *prima facie* case against any of these claims, as argued in the Appeal Brief, at least because the Examiner has not identified a disclosure or suggestion in any reference of any of the additional subject matter recited in any of claims 7–9. Appeal Brief at 13. Consequently, the rejections of claims 7–9 are improper and contrary to law.

III. CONCLUSION

Because each of the pending claims is allowable over the references of record for at least the reasons provided above and in the Appeal Brief, Applicants requests that the Board find all appealed claims allowable.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 01-2215.

Respectfully submitted,
APPLIED MEDICAL RESOURCES

BY _____
Pui Tong Ho
Registration No. 44,155

Telephone: (949) 713-8383